

PART III: CONSUMER INFORMATION

^NSATIVEX[®]

delta-9-tetrahydrocannabinol 27 mg/mL (from Tetranabinex[®] - *Cannabis sativa* L. extract) and cannabidiol 25 mg/mL (from Nabidiolex[®] - *Cannabis sativa* L. extract)

SATIVEX[®] is indicated, as add-on treatment, for symptomatic relief of muscle stiffness in adult patients with multiple sclerosis (MS) who have not responded adequately to other medication and who demonstrate worthwhile improvement during an initial trial of therapy.

SATIVEX[®] may be useful, as add-on treatment, for the symptomatic relief of pain caused by damage to the nerves in adult patients with multiple sclerosis (MS).

SATIVEX[®] may be useful, as add-on pain control treatment, in adult patients with advanced cancer who continue to experience moderate to severe pain even after receiving the highest tolerated dose of a strong opioid pain medication.

SATIVEX[®] has been approved with conditions for the second and third indications above, pending the results of studies to verify its clinical benefit. For more information, patients are advised to contact their health care provider.

What is a Notice of Compliance with Conditions (NOC/c)?

An NOC/c is a form of market approval granted to a product on the basis of **promising** evidence of clinical effectiveness following review of the submission by Health Canada.

Products approved under Health Canada's NOC/c policy are intended for the treatment, prevention or diagnosis of a serious, life-threatening or severely debilitating illness. They have demonstrated promising benefit, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment. In addition, they either respond to a serious unmet medical need in Canada or have demonstrated a significant improvement in the benefit/risk profile over existing therapies. Health Canada has provided access to this product on the condition that sponsors carry out additional clinical trials to verify the anticipated benefit within an agreed upon time frame.

This leaflet is part III of a three-part "Product Monograph" published when SATIVEX[®] was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about SATIVEX[®]. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

SATIVEX[®] is used to relieve muscle stiffness in people with multiple sclerosis who do not get enough relief from other drugs they are using and who find additional relief with SATIVEX[®].

SATIVEX[®] is used to relieve neuropathic pain (pain caused by damage to the nerves), in people with multiple sclerosis (MS). It is also used to relieve pain in patients with advanced cancer who are not getting enough pain relief even at the highest tolerated dose of a strong opioid pain medication.

What it does:

SATIVEX[®] helps to relieve your pain.

When it should not be used:

You should **not** use this product if you:

- Have a known or suspected allergy to any cannabis-based products, propylene glycol, ethanol or peppermint oil.
- Have serious heart disease.
- Have a history of schizophrenia or any other psychotic disorder.
- Are a child or adolescent under 18 years of age.
- Are pregnant or nursing.
- Are female at risk of pregnancy and not using a reliable contraceptive.
- Are male and intending to start a family while on treatment with SATIVEX[®].

Medicinal ingredients:

SATIVEX[®] contains *Cannabis sativa* L. extracts Tetranabinex[®] and Nabidiolex[®] equivalent to 27 mg/mL delta-9-tetrahydrocannabinol (THC) and 25 mg/mL cannabidiol (CBD).

What the nonmedicinal ingredients are:

Ethanol
Propylene glycol
Peppermint oil (flavouring)
This is a full listing of all nonmedicinal ingredients.

Dosage forms:

SATIVEX[®] is provided as a solution in a spray pump. It is contained in an amber glass vial fitted with a metering pump delivering 100 microlitres per actuation (spray). The pump is protected with a plastic cap.

SATIVEX[®] is for buccal use. This means SATIVEX[®] is to be sprayed into the mouth, under the tongue or on to the inside of the cheek. Each 100 microlitre spray contains 2.7 mg delta-9-tetrahydrocannabinol and 2.5 mg cannabidiol.

SATIVEX[®] is available in 10 mL amber glass vials.

The 10 mL vial contains up to 90 metered sprays.

SATIVEX[®] is packed as individual, two, three, four, five, six, eight, ten or 12 vials in each carton.

(Not all presentations may be available in Canada)

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

THC, one of the principal active components of SATIVEX[®], has numerous effects on the central nervous system such as changes in mood, decreased mental performance and memory and altered perceptions of reality. Symptoms such as fainting and interference in the physical ability to carry out complicated tasks have been seen in patients taking SATIVEX[®]. Therefore you should not drive, operate machinery or engage in activities that require unimpaired judgement and coordination.

While taking SATIVEX[®] you should not drink alcohol or take other drugs which may have an effect on the central nervous system such as sedatives or hypnotics, without consulting your doctor, as these products have a further additive effect on some of the symptoms listed above.

BEFORE you use SATIVEX[®] talk to your doctor or pharmacist if you:

- suffer from any allergic reactions
- suffer from epilepsy
- suffer from any liver, kidney or heart disease
- suffer from schizophrenia or depression
- have an irregular heart beat/rhythm, including a fast or slow pulse
- have high blood pressure
- are addicted to drugs or alcohol
- are taking other medicines.

You and your partner must ensure reliable contraceptive precautions are taken during your treatment and for at least three months after you stop taking SATIVEX[®].

There may be a potential for abuse or development of dependence in some individuals with long-term use. Discuss with your doctor.

If you see another doctor or go into hospital, let them know what medicines you are taking.

This product contains approximately 50% v/v ethanol. Each spray contains approximately 0.04 g of alcohol. The usual daily dose will be greater than one spray. It may be harmful for those suffering from alcoholism. The alcohol content should be taken into account when the product is to be used in high-risk groups such as patients with liver disease or epilepsy.

INTERACTIONS WITH THIS MEDICATION

Some drugs may interact with SATIVEX[®]. Therefore, it is important to talk to your doctor or pharmacist about any other medicines you are taking such as but not limited to:

- sedatives
- hypnotics
- fentanyl and the related opioid drugs sufentanil and alfentanil
- amitriptyline
- cannabis (marijuana, pot). Do not smoke marijuana while using SATIVEX[®].
- Alcohol may interact with SATIVEX[®], particularly in affecting coordination, concentration and the ability to respond quickly.

PROPER USE OF THIS MEDICATION

Usual dose:

SATIVEX[®] is to be sprayed into your mouth, under your tongue or on to the inside of your cheek. Do not spray the back of the throat to avoid inhaling and to avoid throat irritation. Vary the location in the mouth into which you spray SATIVEX[®], in order to avoid stinging and discomfort in the mouth. **Do not spray into the nose.**

The dose you require is determined by you. You can determine the dose that best suits you according to the pain relief you experience from taking SATIVEX[®]. Your regular daily dose is determined by increasing your dose gradually over the first few weeks of taking SATIVEX[®].

- On day one, you should take one spray during the morning and one spray during the afternoon/evening. The morning dose can be taken at any time between waking up and 12 noon, and the afternoon/evening dose can be taken at any time between 4 pm and bedtime.
- After the first day you may gradually and carefully increase your intake by **one spray each day**, as needed and tolerated until you experience improved relief of your pain.

- There should be at least a 15 minute gap between sprays.
- When you have found a daily number of sprays that controls your pain, you may adjust the timing between them, depending on how you feel.
- Once you establish the timing and number of sprays that controls your pain, maintain that schedule.
- The best dosing schedule of sprays varies from person to person.

The average dose of SATIVEX® is 4 - 8 sprays per day. The majority of patients need 12 sprays a day or less; there is limited experience with doses higher than 12 sprays a day but you may need a higher number of sprays.

If you experience any bothersome side effects reduce your number of sprays or increase the time between each dose.

Follow these instructions unless your doctor gives you different advice. If there is something you do not understand, ask your doctor or pharmacist. Continue to take this medicine for as long as your doctor prescribes.

HOW TO USE YOUR SPRAY

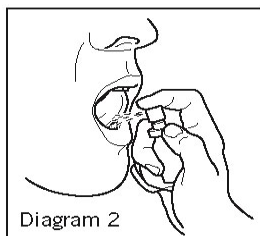
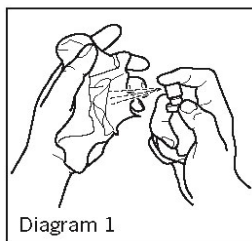
On first opening of a new vial:

Shake the vial gently and remove the protective cap. Place the vial between the thumb and second finger with the first finger placed on the actuator. Press two or three times firmly and quickly into a tissue until a fine spray appears. See Diagram 1.

The medicine is now ready for use.

On normal use:

1. Shake the vial gently before use.
2. Remove the protective cap.
3. Place the vial between the thumb and second finger with the first finger placed on the actuator.
4. Hold the vial in the upright position and direct the spray into your mouth under the tongue or onto the inside of the



cheek. Hold your breath and press firmly and quickly. See Diagram 2.

5. Replace the protective cap.

Important:

If you take 5 sprays each day you will notice after about 17 days mL that the noise of the spray action may change. You may also become aware of a different feeling in your mouth. This is indicating your medicine container is nearly empty. At this point start a new container of medicine.

Keep spray away from eyes. If the spray comes into contact with your eyes or skin it should be washed away immediately with lots of water.

Do not spray near children or pets.

Do not use the spray near an open flame or heat source.

Overdose:

If you accidentally take more than you normally do and you experience severe intoxication reactions, contact your nearest hospital emergency department, regional Poison Control Centre or tell your doctor immediately. Symptoms of intoxication reactions include hallucinations (seeing/hearing things that are not there), delusions (believing things that are not true), anxiety or paranoia (excessive anxiety or fear), increased or decreased heart rate with postural hypotension (feeling dizzy upon standing up). Bring any remaining medicine and the container with you.

The day following an overdose, you should make a follow-up appointment with your usual doctor.

Missed Dose:

If you forget to take a dose, do not worry. SATIVEX® is a medicine that is taken as required. Just take another as soon as you feel you need to.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, SATIVEX® may cause side effects in some patients. They may include dry or sore mouth, feeling or being sick, discomfort and stinging in the mouth or mouth ulcers, tiredness, drowsiness, confusion, dizziness or faintness, disorientation, poor concentration, impaired memory or poor recall, strange ideas, a feeling of unreality, feeling abnormal or drunk, poor balance, slurred speech, feeling people are against you and a feeling of general happiness or a "high" (easy laughing, heightened awareness). Other side effects may include palpitations (rapid heartbeat), vertigo, blurred vision, constipation, diarrhoea, weakness, feeling ill, tooth or mouth discolouration, throat infection, upset stomach, increase or

decrease in appetite, abnormal taste, cough or throat irritation. You may also have side effects of stomach pain or disturbance in attention.

Stinging or discomfort in the mouth may be experienced if SATIVEX® is sprayed in the same place in the mouth on repeated occasions. This is usually overcome by varying the area in the mouth where SATIVEX® is sprayed. Do not continue spraying SATIVEX® onto sore or inflamed areas. If soreness persists inform your doctor.

If unacceptable and unwanted effects occur, stop taking SATIVEX®. These effects can be expected to wear off within a few hours. When returning to your medicine the dose should be reduced or the time between doses increased.

If you suffer any of these side effects and they become troublesome or continue, or you feel unwell in any other way, seek advice from your doctor.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom /Effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Very Common	fatigue	✓		
	dizziness	✓		
Common	fainting			✓
	high or low blood pressure		✓	
	rapid heartbeat			✓
	panic attacks (suddenly being afraid)	✓		
	disorientation/confusion			✓
	depression (sad or low mood)		✓	
	paranoia (excessive fear and anxiety)			✓
	anorexia (decreased appetite)		✓	
	feeling drunk	✓		
	difficulty passing urine	✓		
	falls		✓	
Uncommon	hallucinations (seeing or hearing things that are not there)			✓
	thoughts about suicide			✓
	transient toxic psychosis (losing a sense of reality and not behaving normally)			✓

This is not a complete list of side effects. For any unexpected effects while taking SATIVEX®, contact your doctor or pharmacist.

HOW TO STORE IT

Store upright.

This product is flammable. Replace cap after use.

Store your unopened medicine in a refrigerator (2-8°C). Do not freeze.

Once SATIVEX® is opened, use within 42 days. Opened vials of SATIVEX® may be stored at room temperature (15-25°C).

Shake the vial gently before use.

Do not leave your medicine in a hot place such as in direct sunlight or near a heat source.

Store in a secure place. Do not give your medicine to anyone else.

Do not use SATIVEX® after the expiry date shown on the product packaging.

Return unused portion of SATIVEX® to the pharmacy for safe disposal or dispose of according to local regulations.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

1. Report online at www.healthcanada.gc.ca/medeffect
2. Call toll-free at 1-866-234-2345
3. Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to:
 - Canada Vigilance Program
 - Health Canada
 - Postal Locator 0701E
 - Ottawa, Ontario
 - K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Product Monograph, prepared for health care professionals can be obtained by contacting the importer, Bayer Inc., at: 1-800-265-7382.

Email: canada.medinfo@bayer.com

Bayer Canada web address: www.bayer.ca

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